

REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

I. Anticipation Rejections

- A. Claims 28, 40, & 50 are provisionally rejected under 35 USC 102(e) as being allegedly anticipated by copending Application No. 10/062,447 (i.e., claims 19 and 26).
- B. Claims 28-30, 33, 35-36, 38, 40-42, 44, 46, 48, and 55 are rejected under 35 USC 102(b) as allegedly being anticipated by Holly *et al.*, United States Patent No. 5,476,777.
- C. Claims 28-30, 40-42, 50, and 55 are rejected under 35 USC 102(b) as being allegedly anticipated by Lee *et al.*, Thrombosis Research 82:225-234 (1996).

- II. Claims 28, 40, & 50 are provisionally rejected under the judicial double patenting doctrine as being allegedly unpatentable over claims 19 and 26 or copending Application No. 10/062,447.

I. The Claims Are Not Anticipated

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with any of the references below.

A. Claims 28, 40 & 50 Are Not Anticipated By Appln No. 10/062,477

The Examiner states that "Claims 28, 40, 50 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/062,447 which has a common inventor with the instant application. ... The instant Application claims are to a "prothrombin-related polypeptide." "Related" has been broadly interpreted to encompass proteins encompassed in the blood-clotting cascade." *Office Action* pg. 5. The Applicant disagrees because the Examiner has not provided any evidence showing that one having ordinary skill in the art believes that "prothrombin-related polypeptides" encompass the entire blood-clotting cascade. The Examiner has provided only a conclusory argument, without facts or evidence. The

Examiner is reminded that mere opinion of the Examiner on what one skilled in the art might believe does not count. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, the Applicant has amended Claims 28 and 40 to recite that the polypeptide comprises "... a region that is at least 70% identical to human prothrombin". The Applicant's point to the specification for support of this amendment on pg 17 ln 2 - 6. Claims 38 and 48, therefore, are concomitantly cancelled. Further, the Examiner is requested to note that all the dependent claims have been amended to reflect traditional United States patent claim construction. Other amendments, not associated with the Examiner's arguments, present: i) a "recombinant polypeptide" in Claims 28 and 40 (see Applicants's Specification, pg 29 ln 3-4); ii) a "specific activity between 50% - 150%" in Claims 31 and 43 (see Applicants' Specification, pg 19 ln 12 to pg 20 ln 11); and iii) new Claims 55, 56, and 57 presenting illustrative enzymes and chemicals that may be used for proteolytic processing.

These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicant's business interests, better define one embodiment and expedite the prosecution of this application. The Applicant respectfully requests that the Examiner withdraw this rejection.

B. Claims 28-30, 33, 35-36, 38, 40-42, 44, 46, 48, and 55 Are Not Anticipated By Holly et al.

The Examiner states that "Holly and Foster anticipate [the] claims ... because they teach that human prothrombin or prothrombin-related polypeptides were produced by transgenic yeast. The yeast taught by Holly and Foster are considered to be transgenic as "transgenic" has been defined by the American Heritage dictionary ..." *Office Action pp 8-9*. The Applicant disagrees because the Examiner has not shown that the polypeptide produced by Holly and Foster is identical to that produced by the Applications.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, the Applicant has amended Claims 28 and 40 to recite "... a gla domain". The Applicants point to specification support for this amendment on page 49 ln 14-16.¹ This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicant's business interests, better define one embodiment and expedite the prosecution of this application.

The Applicant respectfully requests that the Examiner withdraw this rejection.

¹ The Examiner has admitted that Holly et al. does not comprise the gla domain. *Office Action* pg 10 ln 1-2.

C. Claims 28-30, 40-42, 50, and 55 Are Not Anticipated By Lee *et al.*

The Examiner states that “Lee *et al.* teach the isolation of human Protein C (HPC), a protein related to prothrombin”. The Applicant disagrees for the reasons stated above. Nevertheless, the Applicant believes that the above claim amendments make this rejection moot. Lee *et al.* does not teach that HPC has a a Gla domain and an amino acid sequence that is at least 70% identical to human prothrombin.

The Applicant respectfully requests the Examiner withdraw this rejection.

II. Claims 28, 40, & 50 Do Not Represent Double Patenting

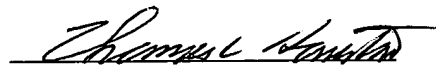
The Examiner states that “Claims 28, 40, 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 26 of copending Application No. 10/062,447.” *Office Action*, pg. 4. The Applicant disagrees and refer to the arguments presented above regarding the Examiner’s anticipation rejection using the ‘447 application. Further, the Applicant believes that this rejection is now moot in consideration of the above claim amendments.

The Applicant respectfully requests that the Examiner withdraw this rejection.

CONCLUSION

The Applicant believes that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 617.984.0616.

Dated: May 31, 2005



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